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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,564	01/27/2000	PASCAL CLAUDE MICHEL LOUVEL	P1047/20008	6103

7590

03/30/2004

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EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/402,564

Applicant(s)

LOUVEL ET AL.

Examiner

Relford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The rejection of claim 9 under 35 U.S.C. 102(b) as being anticipated by Oshlack et al (WO 96/14058) is hereby withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 8 and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack et al (WO 96/14058) as discussed previously, in view of the following comments.
4. Although WO '058 does not teach that the particles are spheroidal, they do teach that the exit port of the extruder can be any shape desired. They further teach that they want to eliminate the spheronization step, which is stated by applicant as well, and it is the position of the examiner that by allowing the exit port of the extruder to be any shape so that the multiparticulates can be any shape, this allows the exit port to be a shape that would form spheroidal particulates. Further, although WO '058 does not specifically refer to a maturing step, it is the position of the examiner that the heating step prior to extrusion, which is discussed by WO 058, reads on applicant's claimed maturing step. Therefore, this invention as a whole would have been prima facie obvious to one of ordinary skill at the time the invention was made.

Response to Argument

5. Applicant's arguments filed November 24, 2003 have been fully considered but they are not persuasive.

6. Applicant argues that the cited prior art discloses a heating step inside the extruding machine and in addition, that in Pill Manufacture (page 27 of the cited art) and Granulation Manufacture (page 44 of the cited art), it is shown that extruder heating zones are used for the heating step for the purpose of rendering extrusion easier, not for manufacturing the mixture. Thus, applicant contends that the step for maturing the mixture takes place outside an extruding machine and is different from heating the mixture for extrusion.

7. In response to the above argument, it is the position of the examiner that heating the mixture inside or outside of the extruder would be obvious to one of ordinary skill in the art. By merely altering the position where the heating takes place (i.e. heating the mixture outside the extruder instead of inside the extruder), does not constitute a claim that recites a feature described as critical to obtain the desired result and is not supported by the enabling disclosure.

8. Claim 8 is rejected under 35 U.S.C. 103(a) on the basis that WO 96/14058 discloses that the process eliminates the spheronization step (page 5, line 25). Applicant argues that the prior art actually proposes to teach the elimination of the need of a spheronization step, that claim 18 of the prior art indicates that sustained-release melt extruded multi-particulates can be non-spheroidal, and therefore do not need to be spheroidal in shape. Applicant contends that applicant's claim 8 is for an apparatus for obtaining spheroidal particles without any additional spheroidal shaping step.

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9. In response to this argument, WO 996/14058 discloses a sustained-release multi-particulate formulation which need not be spheroidized in order to obtain a final dosage form (page 5, lin 25), thus a disclosure for an apparatus that can provide spheroidal particles without any spheroidal shaping step is implicit.

10. Regarding the cutting blade at the exit of the extrusion machine used in WO 96/14058 as deemed equivalent blade set up in applicant's claim 8, applicant argues that applicant's claim 8 requires a tool in the form of blades having a first and second face parallel with one another and so disposed that a cutting edge is provided whereby the shape of the particles obtained by chopping the extruded filaments is directly spheroidal without any additional shaping step.

11. In response to the above argument, it is the position of the examiner that the cited art discloses that the multi-particulate system can be in the form of granules, spheroids or pellets depending on the extruder exit orifice (page 17, lin 28-30). It is the spheroidal product obtained—i.e. spheroidal particles disclosed in the prior art reference that is obvious to one of ordinary skill in the art and not the manner in which the spheroids are obtained as claimed by applicant.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600